Applic Rec'd _____ Hum Subjects Rec'd _____ DUA Rec'd _____ Rev & Approved _____ Added to Req. List _____ Guidelines Sent _____ Networked _____

APPLICATION: COOPERATIVE HUMAN TISSUE NETWORK

I. DIRECTIONS -

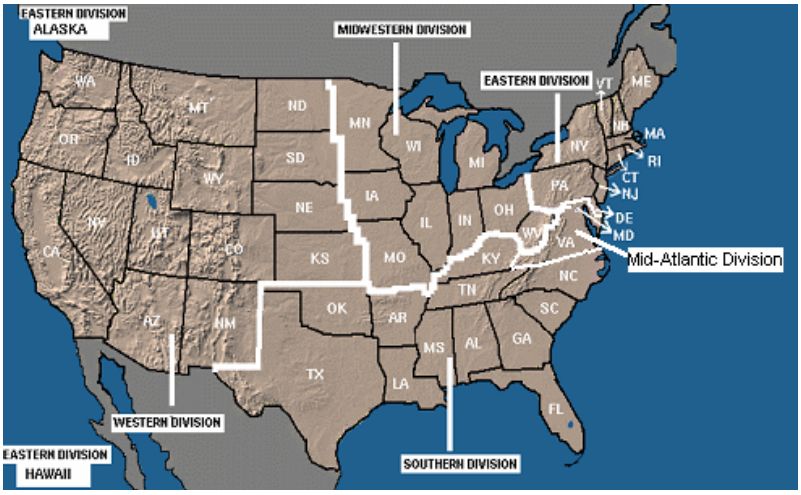
This application is intended for the use and processing of samples utilized by the laboratory and/or personnel that fall under the supervision of the PI listed in the application. Any transfer of samples or aliquots to personnel or laboratories that are not under the supervision of the indicated PI requires the following:

- An explanation of the need to transfer the materials and benefit to the investigator's research
- A copy of the enclosed CHTN agreement page signed by the collaborator
- A copy of the collaborator's IRB approval unless the collaborator is covered under the IRB approval granted for the project proposed in this application

The CHTN does not supply samples to banks solely for distribution to third party researchers; those researchers should be encouraged to apply to the CHTN directly.

The information requested in these forms is necessary in order to document correctly your request for tissue and other services and to ensure that the CHTN operates within the guidelines of the National Cancer Institute. When submitting a written request for services:

A. Please print neatly or type.
B. Please be specific about your requirements for handling tissue samples from the time the specimen is collected until it is delivered to your lab (i.e., need for sterility, transport media, refrigeration status, etc.).
C. Patient identity is confidential. Samples will be coded and delivered at a processing fee of $30/sample for researchers at academic institutions and $70/sample for researchers at non-academic institutions, plus shipping costs. Additional charges may be assessed for special preparation.
D. **Investigators must have human use approval to receive tissue from the CHTN. Either full or expedited approval can be obtained from your Institutional Review Board (Human Use Committee). A COPY OF THE HUMAN SUBJECTS APPROVAL SHOULD BE ATTACHED TO THIS FORM**. An annual human subjects review is required and must be forwarded to the CHTN in order to maintain your eligibility to receive tissue.
E. For pediatric tissue (available nationwide) please complete this application and mail directly to Children's Hospital at the address shown below.
F. For additional information call the Division for your state (see map below). Send completed forms to this division.



EASTERN DIVISION
University of Pennsylvania Med. Center
3400 Spruce Street
566 Dulles
Philadelphia, PA 19104-4283
215-662-4570
215-614-0251 (FAX)
feil@mail.med.upenn.edu

MID-ATLANTIC DIVISION
Cooperative Human Tissue Network
UVA Health System
Department of Pathology
P.O. Box 800214
Charlottesville, VA 22908-0214
434-924-9879
434-924-9438 (FAX)
crumpel@virginia.edu

MIDWESTERN DIVISION
The Ohio State University
Dept. of Pathology, Tissue Procurement
2001 Polaris Parkway
Columbus, OH 43240
614-293-5493
614-293-7013 (FAX)
scott.jewell@osumc.edu

PEDIATRIC DIVISION
Columbus Children's Hospital
700 Children's Drive
Room W135
Columbus, OH 43205
614-722-2714
614-722-2897 (FAX)
brewers@ccri.net

SOUTHERN DIVISION
Tissue Procurement, ZRB 449
University of Alabama at Birmingham
1530 Third Ave. South
Birmingham, AL 35294-0007
205-934-6071
205-934-0816 (FAX)
sexton@uab.edu

WESTERN DIVISION
Vanderbilt University Medical Center
4918 TVC Boulevard
22nd & Pierce Avenue
Nashville, TN 37232-5310
615-322-7486
615-322-4741 (FAX)
kerry.wiles@vanderbilt.edu

II. INVESTIGATOR DATA

A. Principal Investigator: _____

Last Name *First Name* *Middle Initial* *Degree*

Investigator's Title: _____

Primary Mailing Address (Street/Bldg./Room#):_____

_____

Department: _____

Institution:_____

City:_____ State:_____ Zip:_____

Phone (Day):_____ (Nights/Weekends):_____

FAX Number at which you may be notified:_____e-mail_____

Contact Person:_____ Lab/Phone:_____e-mail_____

B. Shipping Address (*if different from above*): _____

Department:_____

Street/Bldg./Room#:_____

City:_____ State:_____ Zip: _____

C. Billing Information: Is a purchase order required for shipment of specimens to your institution?

Yes ____ No____ If so, please list name of contact for P.O.: _____

Name:_____Phone:_____

Currently invoices are included with the tissue shipment to the shipping address listed in section B. If you would like the original invoice to be mailed to another location (eg. your billing department), please enter that address below. A copy of the invoice will also be included with your shipment.

Billing Address (*if different from the shipping address*): _____

Department:_____

Street/Bldg./Room#: _____

City:_____ State:_____ Zip:_____

(Shipping charges will be added to your invoice unless you provide a Federal Express number.)

Federal Express Number _____

III. FUNDING INFORMATION

Tissues will be provided to investigators on a rotating basis in the following priority order:

1. Peer reviewed funded investigators (including Federal and National laboratories)
2. New investigators and academic investigators developing new research projects.
3. Other investigators

A. To help determine your priority, please include <u>your major research grant</u>. Institutional and other funding sources may be listed. If you are currently unfunded, please indicate below:

<u>Funding Source</u> <u>Period of Support</u>

B. Please provide the title and a short research summary of the proposed research on the tissues you are requesting from the CHTN (*use separate page*).

IV. SERVICES REQUESTED *(Please copy this page as needed for multiple requests.)*

A. Human Tissue Specimen Criteria

1. Anatomic Site or Tissue Type:_____

_____Malignant; _____Benign; _____Normal; _____Diseased; _____Other: _____

If malignant is selected, please specify: _____ Primary and/or mets; _____ Primary only; _____ Mets only

_____ Any malignant OR _____ specify type of malignancy:_____

2. Is matched normal tissue from the same patient required? ____ Yes; ____ No; ____ If available
3. Will you accept tissue from patients previously treated with: ____ Radiation; ____ Chemotherapy
4. Must specimen be sterile? _____Yes; _____ No; _____ As clean as possible
5. Gender: ____ Male _____ Female ____ Either
6. Tissue Source:

____ Surgical: Must be frozen within ____hrs of sx OR ____time constraint not applicable

____ Autopsy: Must be collected within _____ hours after death

7. Patient Limitations (i.e., age, race, or other limiting characteristics): _____

_____

8. Amount of tissue required (minimum to maximum size or dimension): _____
9. Frequency tissue is needed:_____
10. Total number of samples needed:_____
11. Requested starting date to receive tissue: _____

B. Preparation and Preservation of Samples (*please mark only those that apply*)

____ **Fresh.** Indicate media requirements:

_____ Transport Media; _____ Saline; _____ Dry; _____ Other: _____

(if preference for transport media, e.g. RPMI, L-15, DMEM, please indicate): _____

Wrap in Gauze? ____Yes ____ No

Add supplements:

___ Antibiotics (indicate type & amount)

___ Fetal Calf Serum (indicate percentage)

___ Fungizone (indicate amount)

Shipping Requirements (wet ice, room temp. etc.)

____ **Frozen.** Indicate freezing requirements (fresh-frozen, OCT, etc.):

____ **Fixed**. Indicate fixative requirements (10% BNF, etc.):

Will you accept Saturday deliveries, if notified? _____ Yes; _____ No; _____ Sometimes, if notified

C. Sample Information Required: *(Anatomic site of tissue, provisional diagnosis, final diagnosis, quality control diagnosis and patient age, sex and race [if available] will be provided for all samples.)* **Additional patient information may be available, but you must request it in this application and justify its necessity for your research. Requests for additional information cannot be accepted after the application is received.**

(NOTE: please notify your division coordinator ASAP if your needs change).

AGREEMENT FOR USE OF TISSUE

The recipient/investigator agrees that the tissues provided by the Cooperative Human Tissue Network (CHTN) will be used only for the purposes specified in this application. The recipient agrees not to attempt to obtain information identifying the individuals providing tissues to the CHTN. The recipient agrees that it shall not sell any portion of the tissues provided by the CHTN, or products directly extracted from these tissues (e.g. protein, mRNA or DNA). The recipient agrees that it shall not transfer tissue (or any portion thereof) supplied by the CHTN to third parties without the prior written permission of the CHTN.

The recipient understands that while the CHTN attempts to avoid providing tissues that are contaminated with highly infectious agents such as hepatitis and HIV, all tissues should be handled as if potentially infectious. The individuals who have supplied tissue to the CHTN have not agreed to have clinical tests performed on this tissue (e.g. for the presence of infective agents such as hepatitis), therefore, the recipient agrees not to perform such tests on the tissues supplied by the CHTN**.** The recipient acknowledges that the institution where the tissue will be used follows OSHA regulations for handling human specimens and will instruct their staff to abide by those rules. The recipient further agrees to assume all responsibility for informing and training personnel in the dangers and procedures for safe handling of human tissues.

Tissues are provided as a service to the research community without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. The CHTN accepts no responsibility for any injury (including death) damages or loss that may arise either directly or indirectly from their use.

The recipient agrees to acknowledge the contributions of the Cooperative Human Tissue Network in all publications resulting from the use of these tissues. Recommended wording to the methods or acknowledgement section is as follows: *"Tissue samples were provided by the Cooperative Human Tissue Network which is funded by the National Cancer Institute. Other investigators may have received specimens from the same subjects."*

When tissue is to be used at State Institutions: The institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage or loss that may arise solely from the receipt, handling, storage and use of tissues received from the CHTN to the extent permitted under the laws of this State. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

When tissue is to be used at U.S. Government Agencies: The US government assumes all risks and responsibilities in connection with the receipt, handling, storage and use of tissues received from the Cooperative Human Tissue Network. The United States assumes liability for any claims, damages, injury or expense arising from the use of the material or any derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chap. 171).

When tissue is to be used by all other institutions: The institution agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of tissues from the Cooperative Human Tissue Network. It further agrees to indemnify and hold harmless the Cooperative Human Tissue Network and the United States Government from any claims costs, damages or expenses resulting from the use of the tissues provided by the CHTN. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

BY MY SIGNATURE I AGREE TO THE TERMS SET FORTH IN THE ABOVE AGREEMENT

_____	_____	_____
Typed Name of Recipient	Agency	Typed Name of Official Authorized to Sign for the Agency
_____	_____	_____
Signature of Recipient/Date	Division or Department	Authorized Signature/Date

UPON RECEIPT OF THESE SIGNED UNDERSTANDINGS AND THE INFORMATION REQUESTEDABOVE, THE COOPERATIVE HUMAN TISSUE NETWORK WILL CONSIDER THIS REQUEST AND ALL FUTURE REQUESTS FOR TISSUE. Specific questions about your application should be directed to your regional coordinator. Other questions may be directed to the NCI Program Director, Dr. Yaffa Rubinstein at 301-496-7147.

DATA USE AGREEMENT BETWEEN COOPERATIVE HUMAN TISSUE NETWORK (CHTN) INSTITUTIONS PROVIDING A LIMITED DATA SET AND LIMITED DATA SET RECIPIENTS

This Data Use Agreement ("Agreement") is designed to permit the use of a Limited Data Set for research pursuant to the Standards for Privacy of Individually Identifiable Health Information, (Privacy Rule) 45 CFR Parts 160 and 164. All terms used in this agreement are as defined in the Privacy Rule.

This Agreement is made and entered into as of this _____ day of _____, 20_____ by and between The Board of Trustees of the University of Alabama for the University of Alabama at Birmingham, the University of Pennsylvania Health System and the University of Pennsylvania School of Medicine, The Rector and Visitors of the University of Virginia for the University of Virginia Medical Center, The Ohio State University, and the Columbus Children's Research Institute, ("Covered Entities"), which operate as various divisions of the Cooperative Human Tissue Network (CHTN) and _____ ("Data Recipient").

1. This Agreement sets forth the terms and conditions pursuant to which the Covered Entities will Disclose certain Protected Health Information (PHI) to the Data Recipient. PHI may include associated histopathologic, demographic, and clinical data that have been rendered a Limited Data set in compliance with 45 CFR 164.514(e) (1).

2. Except as otherwise specified herein, the Data Recipient may make Uses and Disclosures of the Limited Data Set consistent with the purpose of the research as described within their research application to the CHTN.

3. The individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set include the Data Recipient and other researchers or individuals directly involved with the research project described within their research application to the CHTN.

4. The Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.

5. The Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement.

6. The Data Recipient agrees to report to the Covered Entities any Use or Disclosure of the Limited Data Set not provided for by this Agreement, of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor.

7. The Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information.

8. The Data Recipient agrees not to attempt to identify or contact the individual(s) to whom the Limited Data Set applies.

9. This agreement may be terminated by the Covered Entities upon five (5) days written notice to the Data Recipient if the Data Recipient materially breaches any provision contained in this Agreement and such breach is not cured within the five (5) day period. The Data Recipient acknowledges that if efforts to cure the breach are unsuccessful, the Covered Entities may discontinue disclosure of Protected Health Information and report the problem to the Secretary of the Department of Health and Human Services.

10. The terms of this agreement can be changed only by written modification signed by both parties.

Initials of Data Recipient _____

DATA RECIPIENT

_____
Name of Principal Investigator (Typed or Printed)

_____
Authorized Signature

_____
Title

_____
Date